

Award Number: W81XWH-08-2-0045

TITLE: Military to Civilian: RCT of an Intervention to Promote Post-deployment Reintegration

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REPORT DATE: October 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) 01-10-2009		2. REPORT TYPE Annual		3. DATES COVERED (From - To) Sep 2, 2008 to Sep 1, 2009	
4. TITLE AND SUBTITLE Military to Civilian: RCT of an Intervention to Promote Post-deployment Reintegration				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-08-2-0045	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Sayer, Nina, A., PhD Email: nina.sayer@va.gov				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) AND ADDRESS(ES) Minnesota Veterans Research Institute One Veterans Drive Minneapolis, MN 55417				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
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15. SUBJECT TERMS Research Study, Randomized Controlled Trial, Expressive Writing, Internet-based Intervention, OEF/OIF Veterans, Post-deployment Reintegration					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 13	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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## INTRODUCTION:

This study seeks to determine whether Internet-Based Expressive Writing (IB-EW)<sup>1</sup>, a brief, low-cost, easily disseminated, and resource-efficient intervention, can reduce psychological symptoms<sup>2</sup> and improve functioning<sup>3-5</sup> among veterans returning from hazardous deployments. Although Expressive Writing's evidence-base is strong in civilian populations<sup>6</sup>, its efficacy in combat veterans has not been tested. Nevertheless, Expressive Writing, as a highly private, readily accessible, and non-stigmatizing intervention, holds exceptional promise in overcoming barriers to mentally distressed veterans' help-seeking. We expect to further increase the accessibility of the intervention by delivering it over the internet (Internet-Based Expressive Writing). Long term objectives of this line of research are to develop and implement efficient, accessible, and effective interventions that facilitate combat deployment-to-civilian life transitions, thereby reducing risk of long-term, military-related psychopathology and disability. Toward that end, the study will also attempt to identify individual difference characteristics related to the efficacy of the treatment, to indicate who is most likely to benefit from the treatment in order to inform treatment implementation strategies.

## BODY:

This section of the Annual Report is organized according to the study's Year 1 Statement of Work (SOW), which appears throughout this section in underlined font.

### **Milestone 1: Preparing for Implementation (Month 1-12)**

The first 12 months of the project, Milestone 1, were dedicated to making preparations for subsequent implementation portions of the project (see APPENDIX A for the project's full Statement of Work).

#### **Task 1: Obtain required approvals (Months 1-9)**

- **VA and DoD IRB & R&D approvals (Month 1-6)**

We gained VA IRB and R&D approval in August 2008 and annual continuing review approval in July 2009. We obtained IRB approvals for a number of protocol amendments, including a number based on feedback from DoD's human subjects protection agency (Human Research Protection Office [HRPO]), several to accommodate methodological changes identified throughout the implementation planning process, and several documenting administrative updates. HRPO human subjects approval was gained in July 2009.

- **VA Central Office approval to obtain real SSNs and address information (Month 6-9)**

Real SSN access, including access to veteran address information, was granted to study personnel in July 2009.

- **VA Central Office approval to access OIF/OEF Roster (Month 6-9)**

Access to the VA's OEF/OIF roster via the VHA Support Service Center (VSSC) was granted in August 2009 and the first data pull was scheduled for September 2009 (and completed while this report was in preparation subsequent to the reporting period). We also obtained approval to access the DoD's OEF/OIF roster via the Defense Manpower Data Center in August 2009 and are attempting to set up the first quarterly data pull for October 2009.

- OMB Exemption for Research (Month 6)

We obtained OMB exemption status from VA on the basis of the study constituting a randomized controlled trial in February 2009.

- WebOps review of project web application and posting of application on the VA WebOps server (Month 6-9).

We originally proposed to implement this study by launching its online application via VA Web Ops servers. However, our request to use VA Web Ops server space for research on was denied on several occasions, notably in July 2008, November 2008, and February 2009. We continued pursuing access to VA server space.

While attempting to gain approval to use VA server space, we also pursued alternative implementation strategies, including leasing secure server space from a private, external internet hosting company to host the study application. We encountered difficulty gaining authorization to pursue this route, however, on the basis of VA Handbook 6102, which requires all VA business conducted on the internet to use the va.gov internet domain, and VA Handbook 6500, which stipulates that veteran data must remain in the custody of the VA. We attempted to identify equivalent and mitigating security controls to satisfy the security demands of these policy documents. We submitted a waiver request for VA Handbook 6500 in February 2009, but our request was denied and we were referred instead to pursue a waiver of VA Handbook 6102, which was identified as the more directly relevant policy document relating to our pursuit of access to non-VA server space. We learned, however, that there is no existing waiver process for VA Handbook 6102.

While pursuing non-VA server space to host the study's internet application, we also sought to identify other alternative implementation strategies as well, such as using encrypted email exchanges or mailing encrypted removable hardware devices to study participants. However, due to cost, information security, licensing, and practicality concerns, none of these options proved tenable.

As a result of these unsuccessful efforts to identify a viable alternative implementation route, we continued pursuing access to VA server space. Consensus that using VA server space would be the only acceptable option for our project emerged among the study team and local and regional stakeholders, and we were able to obtain the support of a number of stakeholders and leadership personnel at the regional and national VHA and VA levels. As a result of these efforts, we were able to clarify the specific barriers that were preventing our successful attainment of VA server space and overcome these barriers. We submitted a new request for Web Ops web development space in March 2009 and received approval notification for our request from VHA Web Communications later that month.

Upon obtaining approval to use VA Web Ops web development servers, we initiated the process of Web Ops Certification and Accreditation (C&A) of our application, which ensures the performance, security, and integrity of web applications before they are allowed to launch. The C&A process – which entails completion of a number of lengthy documents that require contributions from personnel within our research team as well as at Web Ops, our facility, our regional network, and others – is ongoing. We have been meeting regularly with Web Ops and other relevant personnel to complete the C&A process and its constituent documentation requirements. We anticipate completing the C&A process in October 2009.

Upon being granted access to Web Ops web development server space, we began posting the study application to that server space and updating the study application, for example reprogramming it to reflect new VA website template requirements that had been released during the course of our web server space request process and incorporating procedural changes that had been submitted to and approved by IRB (e.g., minor changes to study measures). As well, the web application was prepared for a requisite Web Ops application scan (“app scan”), which scans the application’s programming code for potential performance or security vulnerabilities as well as its compliance with templating and policy demands. We submitted the first portion of the application (that which will constitute Session One for study participants) for an app scan, reviewed and corrected problems identified in this scan, and submitted this portion of the application for further app scans until it passed. We are currently working on reprogramming the remainder of the study application based on the results of the app scans for the Session One portion in preparation for an app scan of the full application in October 2009.

Task 2: Obtain address information for VA and nonVA users (Month 10-12)

The VSSC and DMDC OEF/OIF roster pulls were not completed by the end of this reporting period. Once both of these rosters are obtained, we will begin the randomization and stratification process to select potential participants to recruit and obtain address information for these individuals. We obtained National Real SSN access in July 2009, including permission to access address information for participant recruitment.

Task 3: Investigator kick-off meeting at Minneapolis VAMC (Month 11)

We held a project kick-off meeting in July 2009 upon successfully acquiring access to VA Web Ops web development servers and initiating programming activities on that server space. Attendees reviewed project developments and discussed upcoming implementation activities.

Task 4: Pilot procedures for recruitment and participant tracking (Months 10-12)

Product: Web-based application and study procedures ready for roll-out

The Web Ops Certification and Accreditation process, which must be completed before the study’s web application is migrated from web development (test) servers to externally-facing web production servers, remains ongoing. Once the study application is allowed to migrate to web production servers –we anticipate this occurring in October 2009 – the study will be piloted with approximately 100-200 pilot participants. The study’s application and procedures will be finalized and ready for roll-out approximately two months after pilot participants begin enrolling.

**KEY RESEARCH ACCOMPLISHMENTS:**

Human Subjects Protection Review

- ◆ Submitted the study protocol to VA IRB and R&D and the USAMRMC Human Research Protection Office (HRPO) at DoD for human subjects protection review.
- ◆ Gained VA IRB and R&D approval in August 2008.
- ◆ Gained HRPO approval in July 2009, after completing a series of requested minor protocol revisions and gaining VA IRB approval of these revisions.
- ◆ HRPO approval was submitted to another DoD agency, the Human Subjects Protection Program (HRPP), in July 2009 as part of the study’s Defense Manpower OEF/OIF data roster request to satisfy their human subjects protection review requirements.
- ◆ Gained VA IRB annual continuing review approval in July 2009.

- ◆ Submitted a number of additional amendments for IRB review, including administrative amendments (e.g., adding new personnel such as the project coordinator to the protocol) and minor revisions to study procedures (e.g., changes to study measures and procedures); all amendments submitted to date have received full IRB approval.

#### Internet Server Space

- ◆ Worked extensively with local and national VA personnel to attempt to gain VA internet server space (through Web Ops) to host the study's software application, as originally proposed. Our request was denied three times. We pursued alternative implementation strategies, such as contracting with private, external internet hosting companies, as well as non-internet based approaches, such as using encrypted email exchanges or encrypted removable hard-drive devices, but none of these options proved tenable. Local and regional consensus emerged that launching the study on VA servers would be the only viable implementation strategy. Upon subsequently gaining concurrence with and support from regional and national leadership, barriers to gaining permission to use VA server space were successfully identified and addressed.
- ◆ Submitted a new request for Web Ops web development space in March 2009 and received approval from the VHA Web Communications office later that month.

#### M2C Internet Application

- ◆ Pursuant to our approved Web Ops web application request, we initiated the process of Certification and Accreditation (C&A) of our application, meeting regularly with Web Ops and other relevant personnel to complete this C&A process and its constituent documentation requirements.
- ◆ Completed documentation required for a Privacy Impact Assessment (PIA) as part of our Web Ops request. We have been working with Web Ops and facility information security and privacy personnel to complete the PIA, and anticipate completing it in October 2009.
- ◆ Initiated a SMART database and user id request, which is required for the submission of C&A and PIA materials for final review.
- ◆ Concurrent with the C&A process for our web application, we prepared the application for a requisite Web Ops "application scan," which checks for potential performance or security vulnerabilities within the program's underlying code as well as its compliance with templating and policy demands. To prepare for the application scan, we uploaded the study application to Web Ops web development (non-externally-facing) servers, updated the web templates used in our program code (VA template requirements have changed since the application was initially programmed), and completed other programming updates. A portion of the application (that which will constitute Session One for study participants) was submitted to an application scan; identified problems were corrected and additional app scans on this portion of the application were completed until all app scan demands for this portion were met. We are currently working on reprogramming the remainder of the study application based on the results of the app scans for the Session One portion and will continue to revise the underlying program code based upon feedback from further app scans.
- ◆ Identified and implemented changes to make to the study application based on administrative and procedural changes made and approved by IRB (e.g., the application had to be reprogrammed to incorporate minor changes we had made to study measures).
- ◆ Initiated additional application programming activities (e.g., programming the participant incentive pages) that we were not previously able to initiate due to uncertainty about the application's ultimate implementation route.

### Veteran Rosters

- ◆ Submitted requests for VA and DoD roster database files for the identification and recruitment of potential study participants, including requests to VA's VHA Support Service Center (VSSC) and DoD's Defense Manpower Data Center (DMDC).
- ◆ Applied for national-level Real SSN privileges from VA's National Data Systems to allow for the inclusion of veteran's actual SSN data in OEF/OIF roster data pulls. Real SSN data will be used for identifying participant address information and management of roster data across data sources via secure crosswalk (e.g., to ensure a veteran who appears in both rosters is not recruited twice).
- ◆ Successfully completed the VSSC roster application process and arranged to obtain our first quarterly VSSC roster pull in September 2009.
- ◆ Obtained DMDC approval to for Defense Manpower OEF/OIF roster data in August 2009 and are attempting to set up our first quarterly data pull for October 2009.

### Other Administrative/Oversight

- ◆ Obtained OMB exemption status in February 2009 on the basis of the study constituting a randomized controlled trial.
- ◆ Submitted quarterly technical progress reports to DoD's U.S. Army Medical Research and Materiel Command.
- ◆ Based on feedback indicating that the term "soldier" is not inclusive of all service branches, we formally changed the name of our study (and internet application) from "Soldier to Civilian..." to "Military to Civilian...."

### Participants and Procedures

- ◆ No participants have yet been enrolled. We proposed to enroll participants during months 13-36 of the study.
  - We will pilot test our web application and study procedures with a limited sample of study participants prior to full recruitment. We anticipate enrolling a limited number of pilot participants (100-200) in approximately October 2009, after we gain final Web Ops C&A approval to migrate the study application from development (test) servers to web production (externally-facing) servers.
  - We expect full recruitment to begin approximately two months after pilot participants begin enrolling.
- ◆ Identified and initiated procedural and administrative preparations to be made for upcoming piloting activities.
- ◆ Reviewed study measures included in the original study proposal, verifying coverage of all content domains of interest and identifying minor revisions to make. Submitted minor measures revisions to IRB for review, gained approval for all changes, and updated the programming code for the study application to reflect these changes.
- ◆ Set up a software program to internally track study participants over the course of their involvement in this longitudinal study (e.g., alerting study team members when a participant is due for a reminder contact).
- ◆ Initiated the development of a contract with the University of Minnesota's Human Research Survey Center to manage the identification and tracking of study participants for whom we do not have current address information, including participants who are in the DoD roster (no addresses) but not in the VA roster (which includes addresses), participants in VSSC whose addresses are outdated, and participants who are lost to tracking over the course of the study.



- ◆ Identified an online retail mechanism through which to purchase gift card codes to use for participant incentives, developed a plan for disseminating these gift card codes to participants consistent with the study protocol, and initiated accounting procedures necessary to make gift card code purchases.

#### Personnel

- ◆ A project coordinator for the study was hired, oriented to the project, added to the IRB protocol, and trained in Fall 2008.
- ◆ Established a Medical Monitor for the project, as required by USAMRMC HRPO, and added him to the study's IRB protocol.
- ◆ Delayed the hiring of a research assistant due to the aforementioned delays in identifying an acceptable route through which to host our online study application. Due to recent progress in this area and a shift into implementation stages of the project (including upcoming recruitment and enrollment of participants), we sought applications for this position in July 2009 and are in the process of filling it.

#### Other

- ◆ Established and held regular project team meetings to coordinate project activities.
- ◆ Held a project kick-off meeting in July 2009 to review project developments and plan upcoming implementation activities.
- ◆ Applied for and obtained a VA-hosted email address and a toll free telephone number for the study.
- ◆ Created and maintained a critical documents binder for the study, including both a paper version and an electronic backup copy.
- ◆ Presented the project at a poster session at the 2009 Military Health Research Forum conference (see REPORTABLE OUTCOMES section below).

#### REPORTABLE OUTCOMES:

Orazem RJ, Sayer NA, Frazier P, Noorbaloochi S, Schnurr P, Litz B, Carlson K, Murdoch M, & Pennebaker J. (2009, September). *Military to Civilian: RCT of a web-based Expressive Writing intervention*. Poster session presented at the annual meeting of the Military Health Research Forum, Kansas City, MO. (See APPENDIX B).

#### CONCLUSION:

As planned, Year 1 of the study was devoted to seeking approvals necessary to implement the study protocol. This study includes an implementation approach – using the internet to deliver an intervention to participants in the context of a clinical trial– that is relatively novel within the VA research system, and we have met significant administrative challenges as a result. At the time of this report, we are nearing the completion of all approvals needed to transition into the implementation stages of the study, which were planned to occur in Years 2 and 3. Prior to rolling-out the study online, several tasks do remain, most notably securing our first DMDC roster pull, completing the VA Web Ops Certification and Accreditation process, and subsequently migrating our study application from web development to web production servers. We anticipate being ready to pilot the study application online in October 2009 and to begin rolling-out full study enrollment approximately two months later, which places us approximately 4 to 6 months behind schedule. We are aware of our study's timeline demands and are sensitive to the need to adhere to the study's Milestones as faithfully as possible. Included in the study's Milestones

are dissemination activities in the final year of the study, to include disseminating scientific findings through manuscript publication activities as well as disseminating administrative and process feedback (“lessons learned”) to relevant VA and DoD stakeholders. As part of the latter, we anticipate providing feedback to stakeholders regarding the institutional barriers to implementation that we have experienced and the need for streamlining a number of relevant administrative processes (most notably, the process for applying for VA web development space for research).

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## APPENDIX A: Statement of Work (SOW)

### **Milestone 1: Preparing for Implementation (Month 1-12)**

Task 1: Obtain required approvals (Months 1-9)

- VA and DoD IRB & R&D approvals (Month 1-6)
- VA Central Office approval to obtain real SSNs and address information (Month 6-9)
- VA Central Office approval to access OIF/OEF Roster (Month 6-9)
- OMB Exemption for Research (Month 6)
- WebOps review of project web application and posting of application on the VA WebOps server (Month 6-9).

Task 2: Obtain address information for VA and nonVA users (Month 10-12)

Task 3: Investigator kick-off meeting at Minneapolis VAMC (Month 11)

Task 4: Pilot procedures for recruitment and participant tracking (Months 10-12)

Product: Web-based application and study procedures ready for roll-out

### **Milestone 2: Data Collection (Month 13-36)**

Task 5: Contact 384 OIF/OEF veterans per month using mail recruitment strategy (Month 13-27)

Task 6: Randomize 78 OIF/OEF per month to three study arms (26 per study arm per month) (Month 13-27)

Task 7: Participants receive copy of study schedule through email (Months 13-27)

Task 8: Each month, 78 participants complete baseline assessments (Month 13-27)

Task 9: Each month, 78 participants in EW and 78 participants in CW conditions complete writing assignments (Month 13-27)

Task 10: Review essays to assess risk of harm to self or other (Month 13-27)

Task 11: Participants receive emails and letters reminding them to complete 3-month follow up assessment. Participants complete 3-month follow up assessment online (Month 16-30).

Task 12: Participants receive emails and letters reminding them to complete 9-month follow up assessment. Participants complete 9-month follow up assessment online (Month 22-36).

Task 13: Contact of participants who fail to complete 3-month and/or 9-month follow up assessments as scheduled (Month 16-36).

### **Milestone 3: Data Preparation (Month 37-39)**

Task 14: Clean and merge assessments for data analysis (Month 37-38).

Task 15: Upload participant's essays into ATLAS.ti for coding (Month 37-40)

Task 16: Extract VA service use data for all participants from VA administrative databases; clean and merge data (Month 39)

Product: Data sets ready for analysis

### **Milestone 4: Data Analysis, Dissemination and Products (Month 40-48)**

Task 17: Conduct statistical analyses to address primary hypotheses (Month 40-42)

Product: Tested web-based intervention for improving outcomes among OIF/OEF veterans with post-deployment reintegration problems that can be used throughout VA for very little expense.

Task 18: Code participant essays (Month 40-43)

Task 19: Analyze coded essays (Month 43-45)

Product: Catalogue of post-deployment reintegration challenges and needs from the perspective of OIF/OEF veterans that can be used to inform other interventions

Task 20: Dissemination and implementation plan meeting in Minneapolis (Month 43)

Task 21: Conduct statistical analyses to address secondary and exploratory hypotheses (Month 43-45)

Task 22: Dissemination Activities/Products and Deliverables (Month 46-48)

- Manuscript preparation (Product)
- Report writing (Product)
- Executive summary preparation and distribution to DoD and VA stakeholders (Product)
- Presentations to DoD and VA stakeholders (Product)
- Presentations at scientific meetings (Product)



# Military to Civilian: RCT of a Web-based Expressive Writing Intervention



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## GOALS

### Short-term Objective

- Test the efficacy of Internet-Based Expressive Writing (IB-EW) in reducing PTSD and related psychiatric symptoms and in improving functioning among OEF and OIF veterans

### Long-term Objective

- Implement efficient and effective interventions that facilitate post-deployment reintegration, thereby reducing risk of long-term, military-related psychopathology and disability

## BACKGROUND

### OEF/OIF Readjustment

- Veterans returning from deployments in Iraq and/or Afghanistan face the interrelated challenges of processing their combat experiences and re-integrating into civilian life<sup>1</sup>
- OEF/OIF veterans carry a high burden of mental disorders such as PTSD and depression<sup>1</sup>
- Even without diagnosable mental disorders, combat exposure may make it difficult for veterans to readjust to civilian life<sup>2-4</sup>

### Pilot Survey of Reintegration Difficulties

- Pilot survey results indicated that an estimated 96% of OEF/OIF combat veterans (n = 754 responses) enrolled in the VA would be interested in services for community reintegration problems
- 97% of participants reported having access to the internet; 93% use it regularly
- Preferences for methods of receiving readjustment services or information are displayed in [Table 1](#)

### Expressive Writing

- Expressive Writing (EW) involves writing about one's deepest thoughts and feelings surrounding a significant life event on 3 to 4 consecutive days<sup>5</sup>
- Although EW's evidence-base for helping people cope with past traumas and major life transitions is strong in civilian populations<sup>6</sup>, its efficacy in combat veterans has not been established
- EW is highly private, readily accessible, and non-stigmatizing; we further capitalize on these features by delivering it over the internet via a secure website

"I did not realize I had so much to say. This hooked my attention very much, so very very much. I was very much into the writing and have a lot more to say. This is very well designed and very pertinent."

-Internet-based Expressive Writing pilot participant

TABLE 1. OEF/OIF Reintegration Services Preferences

How veterans prefer to receive readjustment services or information (n = 754)	Weighted Proportions (%)
At a VA Medical Center	57
Over the internet or web	53
Through the mail	53
Through e-mail	43
At a non-VA Medical Center	33
At or through military unit	32
In a community center	27
Through video conferencing	20
Over the telephone	19

## METHODS

### Participants and Procedures

- Randomized Controlled Trial with three arms:
  - Internet-Based Expressive Writing (IB-EW): Write expressively about your transition from being a service member to being a civilian
  - Internet-Based Control Writing (IB-CW): Write factually about the information needs of new veterans
  - Treatment As Usual (TAU): No writing
- 1,152 nationally-representative OEF/OIF veterans identified through VA and DoD administrative databases
- Outcome measures and intervention sessions all completed online via secure website
- Self-report outcome measures completed (a) pre-intervention and at (b) three and (c) nine months post-intervention
  - Assess demographics, military history, psychiatric symptoms, physical symptoms, functional outcomes, and life satisfaction
- Procedures outlined in [Figure 1](#)

### Piloting the Application on the Intranet

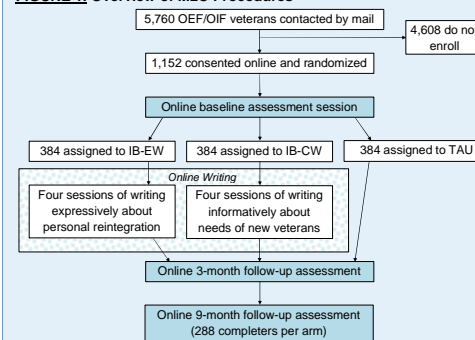
- Piloted the Military 2 Civilian software application for acceptability, readability, and ease of use in a random sample of 8 OIF veterans who lived within 50 miles of the Minneapolis VAMC
- Pilot participants were randomized to IB-EW or IB-CW, completed writing sessions on the intranet at the Minneapolis VAMC under observation by M2C team members, and were interviewed by a member of the study team to identify problems and elicit suggestions
- Resulted in minor changes to the application's wording, formatting, and technical issues based on participant feedback
- Overall, participant reactions were very positive for the study goals, the use of the internet for data collection and intervention delivery, the actual instructions for IB-EW and IB-CW, and the relevance of the study's outcome measures (e.g., see quote, at left)

## METHODS (CONT.)

### Hypotheses

- IB-EW will be associated with improvements in psychiatric and physical symptoms, emotional distress, and reintegration functioning compared to each control group
- Group differences in treatment efficacy at 3-months will be maintained at 9-months
- The efficacy of IB-EW will not vary by gender, race, time since military discharge, or whether or not the veteran is a VA user
- The implementation process of the study will yield "lessons learned" that will be of interest to clinical researchers and VA clinicians; information about implementation processes, resource requirements, and participant experiences will be disseminated

FIGURE 1. Overview of M2C Procedures



## RESULTS

### Status

- Currently in start-up phase, shifting to implementation phase in Fall 2009
- Obtained access to VA server space to host the study's online application
- Gained approval from human subjects protection offices (IRB) at local VA institution, DoD funding institution, and DoD agency maintaining roster of OEF/OIF veterans
- Nearing approval of DoD and VA OEF/OIF roster pulls

### Challenges

- VA regulations require use of VA servers to collect veteran data, but the processes for researchers to obtain access to them are not yet defined
- Following lengthy (15 months) efforts to obtain VA server access, additional time-intensive procedural requirements remain (e.g., Certification & Accreditation)

## NEXT STEPS

- Finalize Certification & Accreditation and gain authorization to launch the study's application on the internet
- Obtain rosters from VA and DoD administrative databases from which to pull sample for recruitment
- Once the study application is functioning online, recruit 300 pilot participants to "fine tune" the application
- Staggered enrollment of 1,152 participants at a rate of approximately 77 per month for 15 months beginning in Fall 2009

## CONCLUSIONS

- Almost all OEF/OIF combat veterans express interest in services for reintegration problems
- Expressive Writing holds promise as an intervention aimed at reducing symptoms and improving functioning among OEF/OIF veterans as they reintegrate following deployment
- OEF/OIF veterans appear comfortable with the idea of using the internet to participate in reintegration services
- Providing interventions such as Expressive Writing over the internet may reduce barriers to accessing services
- The Military 2 Civilian study will report on the efficacy of Internet-Based Expressive Writing, document the nature and scope of problems facing new veterans, and identify what is required to implement this type of intervention within the VA system

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This work is supported by CDMRP #W81XWH-08-2-0045  
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